UNITED STATES DEPARTMENT OF COMMERCE
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08/105444

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/105,444	08/11/93	SPITLER	L 04370003.00

18M2/0815

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GAME EXAMINER	
ART UNIT	PAPER NUMBER
1806	12

DATE MAILED: 08/15/95

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☐ THE PERIOD FOR RESPONSE:

a) ☑ is extended to run 4 MONTHS or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☑ Applicant's response to the final rejection, filed 7/10/95 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☑ Upon the filing an appeal, the proposed amendment ☐ will be entered ☐ will not be entered and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 1-40

   However;

   ☑ Applicant's response has overcome the following rejection(s): claims 1-40. 2ND ¶

4. ☑ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because

   SEE ATTACHED — IT IS NOTED THAT APPLICANT'S SUPPLEMENTAL AMD INCLUDING WRIGHT DECL 1991 HAS BEEN CONSIDERED AS WELL.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

4. The request for reconsideration has been considered but does not overcome the rejection because of the reasons of record.

Applicant argues that there is no reason advanced to support the conclusion that one of ordinary skill would doubt the efficacy of the protocols described; yet admits other methods of have been unsuccessful. Applicant argues that other methods have used antigens from tumor cells rather than from host cells of the organism. This is not found convincing since the antigens encompassed by the claimed invention are the same antigens whether they are expressed on normal, benign or malignant tumor cells. For example, see Chu et al. (U.S. Patent No. 4,446,122, Abstract). In addition, applicant has not provided sufficient evidence to address the Forman factors of record as they apply to prostate-specific antigen-mediated therapy as a therapeutic regimen for human prostate cancer. As applicant admits, there has been development in cancer immunology, the success of cancer vaccines is still forthcoming and not in currently available form. In addition to general cancer vaccines, applicant discloses that prostate cancer continues to be refractory to treatment despite many years of efforts to improve therapy even with current regimens. Therefore, applicant's assertions have not been found convincing.

Applicant argues that In re Brana 34 USPQ2d 1436 (Fed. Cir. 1995) is controlling here. Brana was directed to chemical chemotherapeutic compounds structurally similar to other compounds known in the art and for which animal models were art recognized to be predictive of the therapeutic usefulness and which were, as a class, recognized to be effective in treating tumors. Such is not the case with the instant application which is drawn to cancer vaccines, which do not appear to exist presently in either a pharmaceutical or veterinary setting, and prostate-specific cancer therapy, which is known to be refractory to current therapeutic regimens. Applicant has not provided evidence of a correlation between the instant compositions and methods and cancer vaccines or prostate-specific cancer vaccines. The claimed compositions and methods employ protein/peptide/antibody-based vaccines, which are not structurally related to the compounds of Brana. No evidence demonstrating the similarity in effect and structure of the claimed compounds to other immunotherapeutic agents which operate in a mechanistically similar manner has been presented.

Upon reconsideration and in view of applicant's arguments, filed 7/10/95 (Paper No. 11); the previous rejection of claims 1-40 under 35 U.S.C. § 112, first and second paragraphs, is withdrawn with respect to the second paragraph aspect of this rejection. However the rejection of claims 1-40 under 35 U.S.C. § 112, first paragraphs are maintained for the reasons of record, set forth in the Office Action, mailed 3/7/95 (Paper No. 9). While the examiner acknowledges that the various fragment forms claimed can elicit an immune response; applicant's invention is drawn to eliciting an anti-tumor response with the aspect of

being a vaccine. Eliciting an immune response and eliciting an effective anti-tumor response are not the same. As of record, Ezzell (J. NIH Research, 1995), no one is very optimistic that a single peptide or a virus carrying the gene encoding that peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (page 48, paragraph 6).

Applicant arguments concerning the rejection of claims 1-40 under 35 U.S.C. § 103 as being unpatentable over Chu et al. in view of Dai et al., Deguchi et al., Brown et al., and Alvin are not found convincing for the reasons of record. Applicant argues the references separately and not their combination. Applicant argues that other methods have used antigens from tumor cells rather than from host cells of the organism. This is not found convincing since the antigens encompassed by the claimed invention are the same antigens whether they are expressed on normal, benign or malignant tumor cells. For example, see Chu et al. (U.S. Patent No. 4,446,122, Abstract). In addition, applicant acknowledges that Dai antibodies are mimics not of a prostate-associated antigen, but rather represent the classical approach of using a tumor-associated antigen. Chu et al. and Deguchi et al. clearly teach the prostate-associated and the tumor-associated nature of prostate antigens, including the claimed prostate antigens. Furthermore, applicant has not provided any evidence that the antigen targeted by Dai et al. is not expressed by prostate tissue.

Therefore, applicant's arguments have been fully considered but are not found convincing. The rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Margaret Parr can be reached on (703) 308-2454. The fax phone number for Group 180 is (703) 305-3014 or (703) 308-4227. The fax phone number for Group 180 is (703) 305-3014 or (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

Phillip Gambel, Ph.D.
Patent Examiner
Group 1800
August 10, 1995

M. Parr 8/11/95

MARGARET PARR
SUPERVISOR PATENT EXAMINER
GROUP 1800